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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,205	12/12/2005	Tetsuya Suzuki	2005_1548A	2813

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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,205	SUZUKI, TETSUYA	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,9-12 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9-12 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/04/2008, 12/04/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed 12/04/2008. New claims 21-23 have been added.

Applicant's arguments filed 12/04/2008 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 contains the trademark/trade names methacrylic acid copolymer "L", "S" and "LD". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

name is used to identify/describe methacrylic acid copolymers and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 9-12, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe et al. in view of Remington (1995) and further in view of Mendes et al. (6,468,560).

Abe et al. teach a medicament comprised of alkylenedioxybenzene derivatives of formula I and pharmaceutically acceptable salts thereof; hydrochloride salts are physiologically acceptable salts to be used in the present invention (Abstract, paragraphs [0009-0010] and [0017]). It is preferable to prepare a pharmaceutical composition comprising an active ingredient and one or more pharmaceutical additives (paragraph [0024]). Examples of pharmaceutical compositions include, formulations for oral administration such as tablets, capsules, subtilized granules and the like (paragraph [0024]). Tablets and capsules for oral administration are prepared by using ordinary pharmaceutical additives such as fillers such as cellulose, mannitol and lactose; diluents; disintegrating agents such as starch, polyvinylpyrrolidone. Tablets

may be coated according to a well known method in the art, for example, by using an enteric coating agent, i.e. for controlled, sustained release (paragraph [0025]). Formulations for oral administration can be manufactured according to a method well known in the art. In addition, it is also possible to disperse the active ingredient in a formulation containing a large amount of filler by repetitive mixing (paragraph [0027]).

Abe et al. does not teach a matrix comprised of wax, nor does Abe et al. teach the active agent and wax matrix are coated with a coating agent containing an enteric coating polymer; or the weight percentage of the enteric coating.

Remington teaches that there are four categories of nonimmediate-release delivery systems including sustained, controlled release (page 1661). Some advantages of sustained release include, eliminating or minimizing patient compliance, a decrease or elimination of both local and systemic side effects, and improved efficiency of treatment, i.e. optimized therapy (page 1662). An oral dosage form for sustained release is a matrix device, where a drug is dispersed as a solid in an inert matrix. The three major types of materials used in preparation of oral matrix devices are insoluble plastics, hydrophilic polymers and fatty compounds. Fatty compounds include various waxes such as carnuba wax; the drug is dispersed in the wax matrix and then granulated (page 1666-1667). Film coatings can be applied to pharmaceutical products in order to modify drug release. A controlled release, i.e. delayed release, film coating, such as an enteric coating, will allow the release of a drug to be extended over time by preventing drug release in the upper GI tract. Pharmaceutical formulators now prefer to used synthetic polymers to prepare more effective enteric coatings; the most

extensively used synthetic polymer is cellulose acetate phthalate (pages 1653-1654, Modified-Release Film Coatings).

Remington does not teach that the active agent is an alkylenedioxybenzene derivative of formula I; or the weight percentage of the enteric coating.

Mendes et al. teach pharmaceutical preparations to which is applied an external gastroresistant or enteric coating of suitable thickness; the pellets produced are placed in a hard gelatin capsules and administered to patients in this form (column 1, lines 20-28). The gastroresistant or enteric coating layer contains anionic copolymers of methacrylic acid and ethyl acrylate, such as Eudragit^{R} L30D, L30D-55 and L100-55 (column 8, lines 49-54). The gastroresistant film coats each granule (column 8, line 65). Mendes et al. teach that the granules are comprised of from about 11% to about 32.7% of the enteric coating (column 9, lines 11-50, Table I).

Mendes et al. do not teach a wax matrix granule comprising an alkylenedioxybenzene derivative represented by formula I.

At the time of the invention, it would have been obvious to modify the composition of Abe et al. to include a matrix device and an enteric coating motivated by the desire to modify release of the active ingredient and thereby decrease or eliminate local and systemic effects and improve the efficiency of the treatment as taught by Remington.

Further, it is prima facie obvious to select a compound based on its suitability for its intended use. See MPEP 2144.07. Accordingly, it would have been obvious to use anionic copolymers of methacrylic acid and ethyl acrylate, such as EudragitL30D, L30D-

55 and L100-55 in the weight percentages of Mendes et al. as the enteric coating of the composition suggested by combining Abe et al. and Remington.

In regards to claim 11, the prior art does not explicitly disclose the release rate of the active agent. However, the invention suggested by combining Abe et al., Remington and Mendes et al. is comprised of substantially the same active ingredient, matrix material and enteric film. It would reasonably be expected to exhibit the release rate of the instant claims. Further, routine experimentation by varying the components and configuration of the composition to modify the release of active ingredient and thereby decrease or eliminate local or systemic effects and improve the efficacy of the treatment would reasonably be assumed to produce the release profile of the instant claim.

Further, it would have been obvious to fill a gelatin capsule with the compositions suggested by combining Abe et al., Remington and Mendes et al., for administration since it is an art recognized form of administering controlled release pharmaceuticals as taught by Mendes et al.

Claims 7 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe et al., Remington and Mendes et al. as applied to claims 6, 9, 10, 12 and 21 above, and further in view of Nakamichi et al. (US 5,700,410).

Abe et al., Remington and Mendes et al. are discussed above.

Abe et al., Remington and Mendes et al. do not teach the specific weight percentage of wax.

Nakamichi et al. teach a method of producing a wax matrix for controlled release of pharmaceutically active ingredients (Abstract). The mixing ratio of wax and active ingredient is generally within the range of 1:99 through 999:1, wax:active ingredient (column 3, lines 10-15). The wax that can be used includes waxes of animal or vegetable origin, synthetic waxes and semi-synthetic waxes (column 3, lines 50-52).

At the time of the invention, it would have been obvious to include 5 to 70% or 20% to 50% by weight of wax in the granule suggested by combining Abe et al., Remington and Mendes et al., since an effective range of 1:99 to 999:1, wax:active, is taught in the prior art.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612